Summary of Safety and Effectiveness

APR 2 8 2011

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510 (k) number is: **K102895**

Applicant information:

Date Prepared:	March 1, 2011
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U.S. Consultant	Medvice Consulting, Inc.
Contact Person:	Martin Dalsing
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Device Information:

Device Classification:	Class II
Classification number:	LPL
Classification name:	Lenses, Soft Contact, Daily Disposable
Trade name:	**One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lens

Purpose of 510(k) notification:

1) **Change in lens packaging system to new and innovative, 'Flat Pack Technology'.**

   Was: Traditional, 'Blister' packaging *Now:* Innovative, 'Flat Pack' packaging

Equivalent Predicate Devices:

The **One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lenses are substantially equivalent to the following predicate device:

1. Clear 1-Day (hioxifilcon A), K080632, Manufactured by Clearlab SG Pte Ltd.

Device Description:

The **One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lens is available as a single vision spherical lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The **One Day Flat Pack** Daily Disposable Contact Lens packaging system is designed to reduce lens handling by always presenting the lens anterior side up upon opening, which ensures correct lens orientation for proper eye insertion. The approximately 1mm flat pack packaging system is easily opened and reinforces the single-use factor.

The non-ionic lens material, (hioxifilcon A) is a random copolymer of 2- hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) cross-linked with ethylene glycol dimethacrylate. It consists of 42% hioxifilcon A and 58% water by weight when immersed in a buffered saline solution. The lens is available with a blue visibility-handling tint, color additive 'Reactive Blue # 19', 21 CFR part 73.3121. The United States Adopted Names Council (USAN) has adopted the (hioxifilcon A) name.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index at 21°C:	**1.4011**(wet)
Light Transmission:	**> 95%**
Surface Character:	**Hydrophilic**
Water Content at 21°C:	**58.0 %**
Specific Gravity at 21°C:	**1.086**(wet)
Oxygen Permeability at 34-36°C:	**25.38 x 10^{-11}**(cm^2/sec) (ml O_2/ml x mm Hg), (revised Fatt method).

Substantial Equivalence:

Lenses supplied in the Flat Pack packaging are within established specifications for the lens design and are equivalent to the predicate device lenses supplied in the blister pack packaging. The lens design maintains established physical/chemical characteristics, and are stable and biocompatible with the ocular environment.

- Both the blister and flat pack package have components made from polypropylene and laminated foil.

- Traditional blister pack has its base made from polypropylene with a laminated foil sealed on top. Flat pack package uses the same material with 2 laminated foils and an additional polypropylene disc to ensure correct lens orientation when opened.

The following non-clinical studies demonstrate that lenses supplied in the Flat Pack packaging are substantially equivalent to lenses supplied in the blister pack.

Non-clinical Studies

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lenses packaged in the Flat Pack packaging system. All non-clinical testing was conducted according to valid scientific protocols.

Furthermore, a series of packaging integrity tests, stress tests, and simulations tests were performed on the Flat Pack packaging system to assess overall robustness and demonstrate the integrity of the packaging system.

Test results of the non-clinical testing on the **One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lens demonstrate that:

- Lenses supplied in the Flat Pack packaging system are sterile,
- The packaging material and extracts are not toxic and not irritating, and

- The lens physical and material properties are consistent with lenses packaged in a blister package. See chart below.

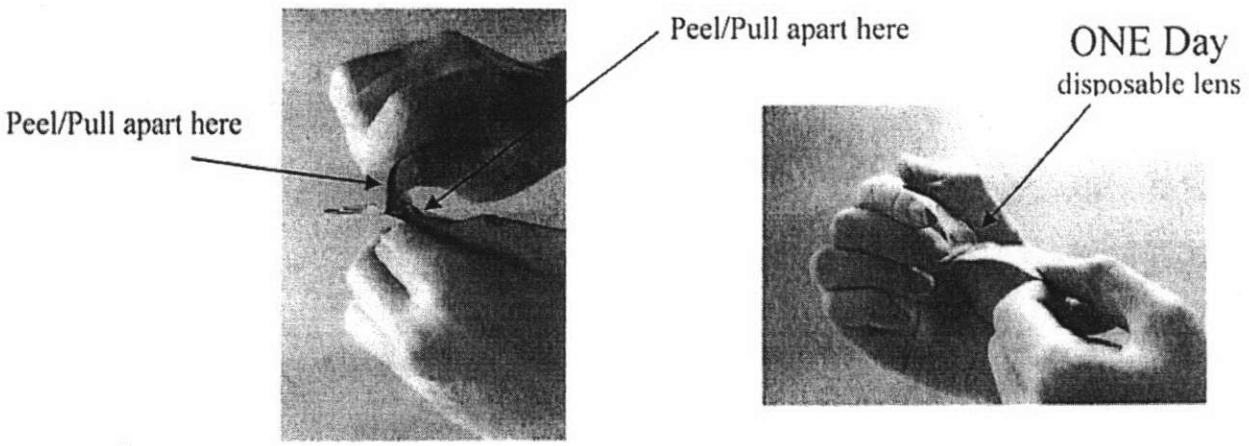
Lens phys/mtl property	One Day Flat Pack	Clear 1-Day –blister pkg.
Lens diameter	14.2	14.2
Lens base curve	8.6	8.6
Lens power	+5D ~ -10D	+10D ~ -20D
Refractive index	1.4011	1.4011
Light transmittance	>95%	>95%
Surface character	Hydrophilic	Hydrophilic
Specific gravity	1.086	1.086
Oxygen permeability	25.38	25.38

Clinical Testing — No clinical data is required for this submission, as the safety and efficacy of the contact lens itself has been previously established in 510(k) K080632.

HOW SUPPLIED/OPENED

Each lens is supplied sterile, in a non-traditional packaging system, the Flat Pack, containing buffered saline solution. Each container of 90 Flat Packs, as well as each Flat Pack is marked with dioptric power, Single Patient Use, R_x Symbol, Sterile Symbol, composition of the lens, manufacturing lot number and expiration date of the lens.

The pack is opened by grasping both top and bottom foil tabs and peeling them apart to fully expose the lens.



Technological Characteristics:

The technological characteristics of the **One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lens, as compared to the predicate device is illustrated in the following table.

Pre-Clinical equivalency /Device	**One Day Flat Pack (hioxifilcon A) New Device**	**Clearl-Day® (hioxifilcon A) Predicate Device**
Intended Use	Indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes.	Indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	Daily Disposable, Soft (hydrophilic) contact lens for single use only.	Daily Disposable, Soft (hydrophilic) contact lens for single use only.
Production Method	Spun-Cast	Spun-Cast
Packaging Method	Flat Pack Technology (FPT)	Blister Pack
Lens Orientation upon opening	Anterior side up	Unknown
FDA Group #	Group #2 >50% Water, non-ionic Polymer	Group #2 >50% Water, non-ionic Polymer
USAN name	Hioxifilcon A	Hioxifilcon A
Water Uptake (%)	58.0%	59.8%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Menicon Company, Ltd.
C/O Mr. Martin Dalsing
Official Correspondent
806 Kimball Avenue
Grand Junction, CO 81501

APR 2 8 2011

Re: K102895
Trade/Device Name: One Day Flat Pack
Regulation Number: 21 CFR 886.5925
Regulation Name: Lenses, Soft Contact, Daily Wear
Regulatory Class: Class II
Product Code: LPL
Dated: April 12, 2011
Received: April 15, 2011

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K102895

INDICATIONS FOR USE STATEMENT

DEVICE NAME: **One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lenses.

INDICATIONS FOR USE:

The **One Day Flat Pack** (hioxifilcon A) Daily Disposable Soft Contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new lens.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use____

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Denise Hampton

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102895